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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting for Software Developers on the Common Formats for Patient Safety Data Collection and Event Reporting

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of public meeting.

SUMMARY: The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to b-26, (Patient Safety Act) provides for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of healthcare delivery. The Patient Safety Act (at 42 U.S.C. 299b-23(b)) authorizes the collection of this information in a standardized manner, as explained in the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the Federal Register on November 21, 2008 (73 FR 70731-70814). AHRQ coordinates the development of common definitions and reporting formats (Common Formats) that allow healthcare providers to voluntarily collect and submit standardized information regarding patient safety events. In order to support the Common Formats, AHRQ has provided technical specifications to promote standardization by ensuring that data collected by PSOs and other entities are clinically and electronically comparable. More information on the Common Formats, including the technical specifications, can be obtained through AHRQ's PSO Web site: <http://www.PSO.AHRQ.GOV>.

The purpose of this notice is to announce a meeting to discuss the Common Formats. This meeting is designed as an interactive forum where software developers and PSOs can provide input on the formats. AHRQ especially requests participation by and input from those entities which have used AHRQ's technical specifications and implemented, or plan to implement, the formats electronically.

DATES: The meeting will be held from 10:00 a.m. to 3:30 p.m. on Friday, April 24, 2015.

ADDRESSES: The meeting will be held at the John M. Eisenberg Conference Center, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; E-mail: PSO@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, skilled nursing facilities, and other health care providers may voluntarily report information regarding patient safety events and quality of care. Information that is assembled and developed by providers for reporting to PSOs and the information received and analyzed by PSOs – called patient safety work product – is privileged and confidential. Patient safety work product is used to identify events, patterns of care, and unsafe conditions that increase risks and hazards to patients. Definitions and other details about PSOs and patient safety work product are included in the Patient Safety Rule.

The Patient Safety Act and Patient Safety Rule require PSOs, to the extent practicable and appropriate, to collect patient safety work product from providers in a standardized manner in order to permit valid comparisons of similar cases among similar providers. The collection of patient safety work product allows the aggregation of sufficient data to

identify and address underlying causal factors of patient safety problems. Both the Patient Safety Act and Patient Safety Rule, including any relevant guidance, can be accessed electronically at: <http://www.PSO.AHRQ.GOV/LEGISLATION>.

In collaboration with the interagency Federal Patient Safety Workgroup (PSWG), the National Quality Forum (NQF) and the public, AHRQ has developed Common Formats for two settings of care – acute care hospitals and skilled nursing facilities – in order to facilitate standardized data collection. AHRQ's Common Formats include:

- Event descriptions (descriptions of patient safety events and unsafe conditions to be reported),
- Specifications for patient safety aggregate reports and individual event summaries,
- Delineation of data elements to be collected for different types of events to populate the reports,
- A user's guide and quick guide, and
- Technical specifications for electronic data collection and reporting.

AHRQ convenes the PSWG to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS – the Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, National Library of Medicine, Office of the National Coordinator for Health Information Technology, Office of Public Health and Science, and Substance Abuse and Mental Health Services Administration – as well as the Department of Defense and Department of Veterans Affairs.

When developing Common Formats, AHRQ first reviews existing patient safety event reporting systems from a variety of health care organizations. In collaboration with the PSWG and Federal subject matter experts, AHRQ drafts and releases beta versions of the Common Formats for public review and comment.

Through a contract with AHRQ, the NQF solicits feedback on the initial and subsequent versions of the Common Formats from private sector organizations and individuals. The NQF, a nonprofit organization that focuses on health care quality, then convenes an expert panel to review the comments received and provide feedback to AHRQ. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, further revises the Common Formats.

The technical specifications promote standardization of collected patient safety event information by specifying rules for data collection and submission, as well as by providing guidance for how and when to create data elements, their valid values, conditional and go-to logic, and

reports. These specifications will ensure that data collected by PSOs and other entities have comparable clinical meaning.

The technical specifications also provide direction to software developers, so that the Common Formats can be implemented electronically, and to PSOs, so that the Common Formats can be submitted electronically to the PSO Privacy Protection Center (PSOPPC) for data de-identification and transmission to the Network of Patient Safety Databases (NPSD).

Common Formats technical specifications consist of the following:

- o data dictionary – defines data elements and their attributes (data element name, answer values, field length, guide for use, etc.) included in Common Formats;
- o clinical document architecture (CDA) implementation guide – provides instructions for developing a file to transmit the Common Formats Patient Safety data from the PSO to the PSOPPC using the Common Formats;
- o validation rules and errors document – specifies and defines the validation rules that will be applied to the Common Formats data elements submitted to the PSOPPC;
- o Common Formats flow charts – diagrams the valid paths to complete generic and event specific formats (a complete event report);
- o local specifications – provides specifications for processing, linking and reporting on events and details specifications for reports; and
- o metadata registry – includes descriptive facts about information contained in the data dictionary to illustrate how such data corresponds with similar data elements used by other Federal agencies and standards development organizations [e.g., HL – 7, International Standards Organization (ISO)].

Agenda, Registration, and Other Information about the Meeting

The 2015 meeting will be an interactive forum designed to allow meeting participants not only to provide input but also to respond to the input provided by others. The meeting agenda will include: an overview of Federal efforts related to the Common Formats; presentations and discussion of implementation of Common Formats Event Reporting – Hospital Versions 1.1 and 1.2; and, a review of data submission both by PSOs and by vendors on behalf of PSOs.

AHRQ requests that interested persons send an e-mail to the PSOPPC at support@psoppc.ORG for registration information. The meeting space will accommodate approximately 150 participants. Before the meeting, a detailed agenda and logistical information will be provided to registrants. Prior to the meeting, AHRQ invites review of the technical

specifications for Common Formats which can be accessed through AHRQ's
PSO Web site at <http://www.pso.AHRQ.GOV/formats/commonfmt.htm>.

Dated: February 3, 2015.

Richard Kronick,
Director.

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